

### **Remarks**

Claims 1-38 are pending in the application and stand rejected. Claims 2, 28, 30, and 39-121 have been canceled, and claims 1, 13, 14, 16, 22, and 29 have been amended. Support for the amendments to claims 1 and 29 can be found in original claims 3 and 29, in the specification (page 16, line 26-page 17), and in the Examples (line 4; page 28, line 18-27). Claims 1 and 16 have been amended to remove language considered indefinite by the Examiner. Claims 13, 14, 22, 27, 32, 34, and 36 have been amended to use proper Markush language. Claims 14 and 29 were amended to correct the dependencies of those claims. Applicant submits that no new matter has been added by the present amendments. Applicant specifically reserves the right to pursue the subject matter of the canceled or amended claims in a related application; the present Amendment is introduced for the sole purpose of focusing the issues in this case and speeding its progress toward allowance. Applicant respectfully requests reexamination and reconsideration of the case in light of the present Amendments and the following remarks. Each of the rejections levied in the Office Action is addressed individually below.

#### **I. Rejection under 35 U.S.C. § 112, second paragraph, as being indefinite.**

Claims 1-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner states that the language “is adapted” in claims 1 and 16 is indefinite because the phrase implies that steps are taken to alter, or make, the implant in a particular way, but the claims do not recite how the composition is “adapted.” Without agreeing with the Examiner’s argument, Applicant has amended claims 1 and 16 to remove the language “is adapted and constructed to be” and submits that this rejection is rendered moot by the present Amendment.

The Examiner also states that claim 1 and its dependents are indefinite for reciting “predetermined conditions” because these conditions have not been adequately defined by the specification. Without agreeing with the Examiner’s argument, Applicant has amended claim 1 to recite “is settable under suitable conditions” and submits that this rejection is rendered moot by the present Amendment.

The Examiner further states that the language “is set” and “becoming set” in claims 11 and 12 is indefinite because it is unclear what these phrases intend to convey as it pertains to the implant. Specifically, the Examiner states that it is not clear if the language means that the implant is no longer formable, or if the implant is set or ready for implantation. Applicant submits that the term “set” is clearly defined in the specification as “the state of a material that has been rendered more resistant to mechanical deformation with respect to a formable state” (page 10, lines 17-18). Applicant, therefore, respectfully submits that the term “set” is not indefinite and requests that the rejection be removed.

The Examiner states that it is unclear whether claims 13, 14, and 22 contain Markush groups, because proper Markush language was not used. Applicant has amended claims 13, 14, and 22 to use proper Markush language and submits that this rejection is rendered moot by the present Amendment.

**II. Rejection under 35 U.S.C. § 102(a) and (e), as being anticipated by Boyce *et al.* (U.S. Patent Application 2002/0035401).** Claims 1-38 are rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Boyce *et al.* (U.S. Patent Application 2002/0035401). The Examiner states that Boyce *et al.* teaches composite osteoimplants comprising bone-derived particles and polymers, wherein the composite is formable during or just prior to implantation. The Examiner states that Boyce *et al.* anticipates claims 1-38.

Without agreeing with the Examiner’s argument, Applicant has amended claim 1 to specify the polymers listed in original claim 29 and described in the specification (page 16, line 26-page 17) and in the Examples (line 4; page 28, line 18-27). As amended, the polymer of the claimed composite implant is selected from the group consisting of starch poly(caprolactone), poly(caprolactone), poly(l-lactide), poly(dl-lactide-co-glycolide), poly(l-lactide-co-dl-lactide), enantiomers of the above, co-polymers of the above, and mixtures of the above. These polymers are characterized by a glass transition or melting temperature that is higher than normal body temperature, for example, higher than 40°C. The present invention encompasses the discovery that composite osteoimplants comprising such polymers possess the unexpected property of being formable and

settable at certain temperatures or when adding particular components, such as increasing the cross-link density of the polymer. The present invention with poly(caprolactone) as an exemplary polymer is described in the Examples. A composite comprising polycaprolactone was manufactured and shown to be formable and settable.

Applicant submits that the claims as amended are not anticipated by Boyce *et al.*, which describes a composite comprising elongate bone-derived particles and a component that may be selected from a laundry list of possible components (paragraphs 62-72). Such components include binders, fillers, fibers, meshes, substances providing radiopacity, plasticizers, biostatic/biocidal agents, surface active agents, *etc.* Polycaprolactone and glycolide-lactide copolymer are mentioned as possible binders (paragraph 62), but Boyce *et al.* does not provide any characterization of these polymers or any description of how they would behave as components of a composite comprising bone-derived particles.

Furthermore, the only composite manufactured in the Examples of Boyce *et al.* is bone-derived elements and a glycerol/water carrier. Glycerol has a melting temperature of 18°C and a glass transition temperature of -83°C and is liquid at room temperature. Therefore, glycerol is and not formable and settable as described in the present invention, which utilizes polymers characterized by a glass transition or melting temperature that is higher than normal body temperature, for example, higher than 40°C.

There is no teaching or suggestion in Boyce *et al.* relating to composites that are formable and settable. Boyce does not disclose the present invention, in which composites are formable and settable at certain temperatures or when using particular polymers. The behavior and characteristics of composites comprising poly(caprolactone) or the other polymers recited in claim 1 are not taught or predicted by Boyce *et al.* and are, therefore, surprising and unexpected. Applicant submits that the claims as amended are not anticipated by Boyce *et al.* and, therefore, respectfully requests that the rejection be removed.

**III. Double patenting.** Claims 1-38 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-83 of copending U.S. Patent Application USSN 10/681,651 and over claims 51-116 of

copending U.S. Patent Application USSN 10/639,912. Applicant respectfully defers further comment on this rejection until the claims of either application have been found to be patentable.

Applicant, therefore, respectfully submits that the present case is in condition for allowance. A Notice to that effect is respectfully requested.

If, at any time, it appears that a phone discussion would be helpful, the undersigned would greatly appreciate the opportunity to discuss such issues at the Examiner's convenience. The undersigned can be contacted at (617) 248-5215.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,



---

C. Hunter Baker, M.D., Ph.D.  
Registration Number: 46,533

Choate, Hall & Stewart LLP  
Two International Place  
Boston, MA 02110  
t (617) 248-5215  
f (617) 248-4000  
cbaker@choate.com  
Date: November 27, 2006